UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC., *et al.*,	:	
	:	
Plaintiffs,	:	Case No. 21-cv-4106 (AMD) (RER)
	:	
v.	:	
	:	
SAFE CHAIN SOLUTIONS, LLC, *et al.*,	:	
	:	
Defendants.	:	
	:	
	:	

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO SCRIPTS' MOTION TO LIFT OR AMEND THE ASSET FREEZE

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Plaintiffs Gilead Sciences, Inc., Gilead Sciences Ireland UC, and Gilead Sciences, LLC (together, "Gilead" or "Plaintiffs") respectfully submit this memorandum of law in opposition to the motion of Defendant Scripts Wholesale, Inc. ("Scripts") to lift or amend this Court's Asset Freeze Order.

INTRODUCTION

While stylized as a motion to vacate or amend the asset freeze, Scripts' brief does not contain a single factual allegation, much less any substantiated facts, concerning its financial condition, its expenses, or the illicit profits that have been frozen. Instead, Scripts sets forth meritless legal arguments that it cannot be held responsible under the Lanham Act for selling counterfeits. Scripts has completely failed to meet its burden of proof, and deliberately so: Scripts has made the strategic decision to rely entirely on its contention that it has no burden of proof, on the theory that the asset freeze is a TRO that must now be reargued *de novo*, some 19 months after it was ordered. That argument is squarely rejected by controlling authority from the Supreme Court and the Second Circuit. The Asset Freeze Order is a preliminary injunction: as a matter of law, it cannot be anything else. Both parties agree that the party challenging a preliminary injunction asset freeze bears the burden of proof, and there can be no question that Scripts has not met that burden.

In any event, the record as it stands today contains substantial additional support for the asset freeze, beyond what it did at the time of the order. Facts uncovered since that time show that Scripts, leveraging its pharmaceutical distribution licenses for wrongful gain, has been knowingly trafficking in counterfeit Gilead-branded HIV medication for at least five years – making Scripts by far (to Gilead's knowledge) the longest-running and highest-volume counterfeiter of Gilead-branded HIV medication in this action. Since filing its papers in support of the original asset freeze against Scripts, Gilead has learned that prior to selling the counterfeits

described in the Complaint, Scripts purchased large quantities of counterfeits from a different supplier, Mainspring Distribution LLC ("Mainspring"). It was only after Mainspring's principals were arrested and convicted for running a "black market" HIV medication counterfeiting ring whose schemes including manufacturing counterfeits by placing counterfeit Gilead HIV medication labels on other bottles of medication and filling empty bottles with fake pills, that Scripts turned to the counterfeiting ring described in the Complaint. Scripts maxed out its credit cards purchasing $34 million in black-market counterfeit Gilead drugs from Mainspring, as well as providing an additional $5 million "advance" to finance the operation and speed the production of the counterfeits – an investment Scripts promptly lost when Mainspring's principals were indicted.

The majority of the counterfeit Gilead-branded HIV medication Scripts sold in this case were manufactured by starting with Gilead bottles (empty or full) purchased directly from vulnerable patients, such as substance users or persons who are homeless. Already-dispensed bottles purchased from patients can only end up back in the U.S. drug supply chain, and resold as genuine and safe medicine to pharmacies, by manufacturing counterfeit pedigrees that fraudulently state the bottles were purchased from a legitimate supplier, not on a street corner. During its five-year run, Scripts sold over 54,000 counterfeit bottles of Gilead-branded medication for over $137 million to pharmacies across the United States. Gilead has submitted proof that **every one** of those bottles was sold with a counterfeit pedigree to conceal their illicit origin and defraud patients who received these counterfeits from pharmacies. In fact, recently uncovered evidence shows that Scripts' owner, Defendant Diamantstein, worked directly with the street-level collectors, and **personally directed the creation of hundreds of counterfeit pedigrees for those bottles repurchased from patients to manufacture and ready the**

counterfeits for pharmacy shelves, including dictating the fraudulent chain of custody that should appear on those pedigrees.

Scripts does not – because it cannot – dispute that all of the purported "genuine" Gilead products it sold bore fake pedigrees. Instead, Scripts downplays the fake pedigrees it created, claiming that they are just regulatory documents irrelevant to the Lanham Act and arguing, contrary to the law, that it cannot be sued for selling medication (presumably even when that medication was illegally purchased from patients) with counterfeit pedigrees. But selling prescription drugs repackaged with false pedigrees as genuine violates ***both*** the Drug Supply Chain Security ("DSCSA"), which requires the pedigrees, ***and*** the Lanham Act, which prohibits the sale of counterfeits and products with a false designation of origin. Gilead's authentic pedigrees are part of Gilead's product package. Authentic pedigrees are how pharmacies and other buyers know that medications are authentic and were safely stored and transported, and how Gilead maintains a secure supply chain and tracks bottles to be able to quickly respond in cases of tampering, mishandling, and other potential safety issues. Scripts created thousands of counterfeit pedigrees to help manufacture the counterfeits, copying Gilead's authentic pedigrees (including Gilead's trademarks) but listing fake sales that Gilead never made, to trick their customers into believing Scripts was selling authentic Gilead-branded medications. The reality is that Scripts has ***never*** sold a single authentic Gilead medicine, and its counterfeiting has undermined the security of the pharmaceutical supply system and caused incalculable harm to patients. Scripts' motion should be denied.

LEGAL STANDARD

I. Scripts Bears the Burden of Showing Why the Asset Freeze Order Should Be Amended, and They Have Not Attempted to Do So

The Asset Freeze Order is a preliminary injunction, and it is black-letter law that a party moving to vacate or amend a preliminary injunction bears the burden of proving the change in circumstances that would justify modifying the injunction. *E.g.*, *Klipsch Grp., Inc. v. Big Box Store Ltd.*, 2012 U.S. Dist. LEXIS 153137, at *27 (S.D.N.Y. Oct. 24, 2012); *Ideavillage Prods. Corp. v. Bling Boutique Store*, No. 16-CV-9039 (KMW), 2017 WL 1435748, at *6 (S.D.N.Y. Apr. 21, 2017) ("Moving Defendants contend that the Asset Freeze Order should be lifted, without demonstrating that their assets are not wrongfully derived from the sale of counterfeit[] products, and without showing that they would not hide or dissipate these profits…. Defendants have failed to meet their burden. Thus, the Court will not lift or modify the Asset Freeze Order.") The case law cited in Scripts' Motion is in accord. *Spin Master v. Aciper*, 2020 U.S. Dist. LEXIS 206278 at *9 (S.D.N.Y. Nov. 4, 2020) (citing *N. Face Apparel Corp.*, 2006 U.S. Dist. LEXIS 14226 at *3 (S.D.N.Y. Mar. 30, 2006)); *Cartier Int'l B.V. v. Liu*, 2003 U.S. Dist. LEXIS 6381 at *1 (S.D.N.Y. Apr. 17, 2003).

Scripts introduces no evidence, makes no factual assertions, claims no financial hardship, and generally makes no attempt to meet its burden. Instead, Scripts puts all its eggs in one basket: arguing that the Asset Freeze Order issued nearly two years ago is a Temporary Restraining Order, and thus the Court must redetermine the entire freeze *de novo*, with Gilead bearing the burden. As a matter of settled law, Script is incorrect.

A. Procedural History of the Asset Freeze Order

The relevant procedural history is straightforward. On October 16, 2021, this Court entered two separate *ex parte* Temporary Restraining Orders: first, a TRO order prohibiting

Scripts from buying or selling any Gilead-branded products, and second, a TRO freezing Scripts' assets (the "Asset Freeze Order"). Dkt. Nos. 166, 168. The TRO prohibiting sales of Gilead products included a set preliminary injunction hearing date of October 27, 2021, with opposition papers due October 20; the Asset Freeze Order did not list a hearing date. *Id.* But on October 19, the day before their opposition was due, Scripts submitted a Stipulation and Proposed Order, which the Court so-ordered the following day, wherein Scripts stipulated to extending the TRO prohibiting Scripts' sale of Gilead products through November 18, 2021, and the preliminary injunction hearing for that TRO was adjourned one month to November 19. Dkt. No. 181. The so-ordered stipulation did *not*, however, also extend the Asset Freeze Order to November 18 or any other expiration date, nor did it set a hearing for the Asset Freeze Order. Rather, it provided for the immediate release of all but one of the frozen accounts, giving Scripts immediate access to $2.4 million in cash, and further stated that "the provisions of the Court's Asset Freeze Order shall remain in effect" indefinitely.

Plaintiffs and the Scripts Defendants subsequently entered into several additional stipulations, each so-ordered by the Court, extending the TRO prohibiting the sale of Gilead products and the related preliminary injunction hearing. *See, e.g.*, Dkt. Nos. 252, 375. Each of those successive extensions of the TRO was expressly limited to the prohibition on the sale of Gilead products; none of them even reference the asset freeze. The TRO prohibiting the sale of products thus remains a TRO, extended by stipulation of the parties. The Asset Freeze Order has **never** been extended by stipulation or otherwise of this Court, and has simply remained in effect for the past 19 months.

B. Controlling Authority Holds that the Asset Freeze Order Automatically Converted to a Preliminary Injunction, and Must be Treated As Such for All Purposes

Scripts argues that for the last 19 months, the Asset Freeze Order has remained a TRO. Without a stipulated extension, there is no such creature as a 19-month-old TRO under federal law. Because the parties never stipulated to an extension of the Asset Freeze Order, the only thing it can be at this point is a preliminary injunction.

1. A TRO that Is Not Extended by Stipulation Automatically Becomes a Preliminary Injunction After 14 Days

The Supreme Court has held that any TRO not extended by stipulation of the parties, and remaining in effect longer than the time allowed by Rule 65, automatically converts into a preliminary injunction. *Sampson v. Murray*, 415 U.S. 61, 85-88 (1974).

In *Sampson*, the question of whether the lower court's order was a TRO or preliminary injunction was a jurisdictional one: injunctions are reviewable on appeal, but TROs are not. Subsequent litigants have thus raised the question of whether the *Sampson* Court held that a TRO in fact converts to a preliminary injunction on the fifteenth day, or whether the Court merely held that the TRO should be treated as an injunction for purposes of its reviewability on appeal. The Second Circuit addressed this question, and held that the TRO does convert to a preliminary injunction for all purposes: "The appellants urge that the holdings of *Sampson* … should be limited to the proposition that TROs extended past the time limits imposed by Rule 65(b) are merely considered preliminary injunctions for purposes of appealability. This interpretation has no merit." *In re Crawford*, 329 F.3d 131, 137-38 (2d. Cir. 2003). The Second Circuit expressly adopted the reasoning of the Eleventh Circuit, which also held a TRO that extends beyond fourteen days automatically becomes a preliminary injunction for all purposes: "a preliminary

injunction is a preliminary injunction." *Id.* at 137 (quoting *Levine v. Comcoa Ltd.*, 70 F.3d 1191, 1193 (11th Cir. 1995)) (emphasis added).

The only alternative to a TRO converting to a preliminary injunction on the fifteenth day is to hold that the TRO became completely null and void after the fourteenth day. *See id.* at 136-38 (citing *Granny Goose Foods, Inc. v. Bhd. of Teamsters*, 415 U.S. 423 (1974)). As the Second Circuit explained in *Granny Goose* – a case that preceded *Sampson* – the Supreme Court held that where the TRO has no built-in expiration date and the defendant "had no reason to believe that a preliminary injunction of unlimited duration had been issued," and so "could reasonably assume the order ha[d] expired within the time limits of Rule 65," the TRO did in fact so expire. *Id.* (quoting *Granny Goose*, 415 U.S. at 445 (alterations in original)). The Second Circuit held the reasoning in *Granny Goose* cannot apply where the parties had notice that the provisions contained in the TRO would continue indefinitely, such as when the TRO was amended to explicitly state those provisions would continue to remain in effect. *Id.* Where the parties have such notice that the effects of the TRO will continue, it does not expire, but rather converts into a preliminary injunction. *Id.*

Here, the Asset Freeze Order was amended to explicitly state "the provisions of the Court's Asset Freeze Order shall remain in effect" – in other words, continue indefinitely – and the parties have both acknowledged the freeze is in fact still in effect. Scripts' consistent position has been that the Asset Freeze Order in effect. Under *Sampson* and *Crawford*, as a matter of law, the Asset Freeze Order long ago converted into a preliminary injunction.

2. Under Identical Facts, Courts Have Found a Motion to Vacate an Asset Freeze to Be a Motion to Amend a Preliminary Injunction

The Eleventh Circuit has examined facts identical to those at issue in the instant motion, and concluded that a motion to vacate an asset freeze issued *ex parte* must be considered a

motion to amend a preliminary injunction. *AT&T Broadband v. Tech Commc'ns, Inc.*, 381 F.3d 1309 (11th Cir. 2004). In *AT&T*, as here, the district court entered an *ex parte* TRO prohibiting the sale of infringing product, and a separate *ex parte* TRO freezing the defendant's assets. *Id.* at 1312-1313. And in *AT&T*, as here, the defendant submitted a stipulation just before the scheduled preliminary injunction hearing. In that stipulation, the *AT&T* defendant agreed to convert to a preliminary injunction the prohibition on his sale of the infringing products, and also agreed to "a continuation of the asset freeze," with a separate provision stating "Defendants[] reserve the right to file a Motion to Dissolve the Asset Freeze at a later date." *See* Waters Decl. Ex. 73.

The defendant in *AT&T* proposed, and the district court so-ordered, an order preliminarily enjoining the sale of the infringing product, but that order did **not** amend or otherwise address the TRO asset freeze order, which simply continued to remain in effect. *Id.* Ex. 74. Approximately a month later, the defendant filed a motion to vacate the asset freeze; the district court denied the motion, and defendant appealed. 381 F.3d at 1314.

That motion to vacate the asset freeze order in *AT&T* was in the same procedural posture as the instant motion to vacate filed by Scripts. In both cases the parties separately resolved an *ex parte* TRO prohibiting the sale of product, but simply allowed the *ex parte* Asset Freeze Order to stay in effect. Both Scripts and the defendant in *AT&T* agreed that the asset freeze would continue, while expressly reserving their right to later move to vacate it. Compare Dkt. No. 181 ¶¶ 3, 4 (Scripts stipulating that "the Court's Asset Freeze Order shall remain in effect" while "reserving [its] rights to further move to amend the Asset Freeze Order") *with* Waters Decl. 74 at ¶¶ 4, 6 (defendant in *AT&T* stipulating to a "continuation of the asset freeze" while "reserv[ing] the right to file a Motion to Dissolve the Asset Freeze at a later date."). And in both cases, the

Court did not hold a preliminary injunction hearing prior to the filing of the motion to vacate the freeze.

On appeal, the Eleventh Circuit directly held that in these circumstances, the defendant's motion to vacate is "**a request for the modification of a preliminary injunction**," because the TRO asset freeze had converted to a preliminary injunction when it continued beyond the time limit prescribed by Fed. R. Civ P. 65(b)(2). *AT&T*, 381 F.3d at 1314 (emphasis added). Just as in *Crawford* and *Levine*, the Eleventh Circuit in *AT&T* held it was appropriate for the *ex parte* asset freeze to automatically convert into a preliminary injunction because the defendant clearly had notice that the *ex parte* asset freeze was to continue indefinitely: (1) the plaintiff had "requested relief that would extend well beyond ten days" and the relief in fact extended beyond ten days; (2) the defendant's notice was obvious from the fact that he stipulated to the continuation of the freeze; and (3) the asset freeze was an alteration of the status quo, such that defendant knew the injunction was affecting his rights. *Id.* The exact same is true here – and the Second Circuit has affirmatively adopted the Eleventh Circuit's holding that a TRO that extends beyond 14 days converts to a preliminary injunction for all purposes. Therefore, Scripts bears the burden of proof of showing that the preliminary injunction Asset Freeze Order should be amended.

C. Scripts In Fact Stipulated to a Preliminary Injunction In Exchange for the Release of $2.4 Million

Because the Asset Freeze Order must, under controlling caselaw, be a preliminary injunction, Scripts' intent is ultimately irrelevant. But the reality is that Scripts voluntarily gave up its right to challenge the Asset Freeze Order *de novo* as a TRO as part of a negotiated compromise: certain of the frozen funds would be immediately released, and a single account would remain frozen for the duration of the litigation.

Specifically, Scripts stipulated, as have several other defendants, that one account would remain frozen, and the others, holding over $2.4 million in cash, would be immediately unfrozen. Dkt. No. 181 ("Plaintiffs and the **Scripts Defendants have agreed** to release all funds from fourteen of the fifteen disclosed frozen accounts, totaling approximately $2.4 million, for the Scripts Defendants' immediate use, **while maintaining the freeze on the Scripts Savings account, ending in 2120**"). The so-ordered stipulation further provided that "except to the extent inconsistent with this Order, the provisions of the Court's Asset Freeze Order shall remain in effect." *Id.* An express agreement to keep certain funds indefinitely frozen, as a *quid pro quo* for agreeing to release other funds, is a stipulated preliminary injunction. Scripts cannot be heard now to complain that it did not have a chance to challenge *de novo* the order to which it stipulated.

This Court has in fact already held that, in this procedural posture, the defendant moving to amend the Asset Freeze Order bears the burden of proof. At the beginning of the case another major Distributor Defendant, Safe Chain, entered into a similar so-ordered stipulation, using substantively identical language, that modified the Asset Freeze Order by releasing certain accounts while maintaining the freeze on other accounts. Dkt. No. 28. The Safe Chain Defendants' stipulation, like Scripts, concluded by providing that "except to the extent inconsistent with this Order, the provisions of the Court's Asset Freeze Order shall remain in effect." *Id.* Of course, the fact that the Safe Chain Defendants stipulated to a preliminary injunction asset freeze did not preclude them from later moving to amend it. And when the Safe Chain Defendants filed such a motion to amend the asset freeze, this Court expressly held that the Safe Chain Defendants bore the burden of proof of demonstrating why the freeze should be amended. Dkt. No. 259. The same is true with regard to Scripts' instant motion.

D. Scripts Makes No Attempt to Meet Its Burden, and So Its Motion Must Be Denied Out of Hand

In its motion, Scripts introduces no evidence and makes no arguments that circumstances have changed since the Court issued the Asset Freeze Order. It makes no argument and offers no proof that Gilead has frozen more than Scripts' counterfeiting profits. In short, Scripts makes no effort to meet its burden on a motion to vacate or amend a preliminary injunction. Its attempt to argue *de novo* the likelihood of success of Gilead's claims, and its complaints that the Asset Freeze Order should never have been issued in the first place cannot meet Scripts' burden and are, irrelevant to this motion to vacate. If Scripts believes it can meet its burden, it can file another motion supported by competent evidence. The instant motion is utterly unsupported, and the Court should deny it out of hand.

E. If the Asset Freeze Were a TRO, Gilead Would Be Entitled to Question Mr. Diamantstein at the Preliminary Injunction Hearing

Assuming *arguendo* that the Asset Freeze Order were still somehow a TRO (it is not), then Scripts' motion to vacate that order must be considered an opposition to the entry of a preliminary injunction asset freeze. If that were the case, Gilead would be entitled to an evidentiary preliminary injunction hearing. *See, e.g.*, *Motorola Credit Corp. v. Uzan*, 2003 WL 21373463, at *2 (S.D.N.Y. June 12, 2003) ("It is well established that motions for preliminary injunctions should not be resolved on the basis of affidavits which evince disputed issues of fact [and] [n]ormally an evidentiary hearing is required to decide credibility issues.") (quoting *Forts v. Ward,* 566 F.2d 849, 851 (2d Cir.1977)); *see also Charette v. Town of Oyster Bay*, 159 F.3d 749, 755 (2d Cir. 1998) ("A party may, of course, waive its right to an evidentiary hearing but it is not entitled to have the court accept its untested representations as true if they are disputed."). This Court in fact granted Gilead the right to take expedited discovery, including depositions, in part to allow it to prepare for preliminary injunction hearings. Dkt. No. 48.

Scripts' owner and principal, Steven Diamantstein, controlled Scripts' finances and was personally involved in Scripts' manufacturing and trafficking of counterfeit Gilead-branded medications for at least five years. Gilead cannot present Mr. Diamantstein's deposition testimony, because he successfully moved to delay his deposition due to a pending criminal investigation against him concerning his sale of counterfeit Gilead-branded medications. Apr. 27, 2023 Text Order. But this Court's order did ***not*** exempt Mr. Diamantstein from giving testimony if called at an evidentiary hearing.

Mr. Diamantstein cannot claim surprise at being called to give such testimony at a preliminary injunction hearing: he has forced that hearing to occur by (1) filing the motion to vacate after learning of the criminal investigation against him; (2) refusing Gilead's request to delay the motion to vacate until after the stay on his deposition testimony expires; and (3) taking the position that the asset freeze is a TRO and Gilead must make an evidentiary showing in response to his motion. It would, of course, significantly prejudice Gilead to allow Mr. Diamantstein to press forward with a preliminary injunction hearing while depriving Gilead of the opportunity to present his testimony, all because Mr. Diamantstein's willful counterfeiting has made him the target of a criminal investigation.

If the Court finds, as Gilead respectfully submits it must, that the Asset Freeze Order is already a preliminary injunction, then of course there is no need for a preliminary injunction hearing and the issue is moot. But if the Court were to hold the Asset Freeze Order is a TRO, then Gilead invokes its right to an evidentiary preliminary injunction hearing and gives notice of its intent to examine Mr. Diamantstein at that hearing.

STATEMENT OF FACTS

This Court has already found that the facts Gilead presented in support of its original application for the Asset Freeze Order, submitted over 19 months ago, were sufficient to support

the injunctive relief Gilead requested. Scripts does not challenge **any** aspect of that original record. That undisputed record, which Gilead incorporates by reference here, is on its own sufficient to deny Scripts' motion to vacate. But as discovery has continued and Gilead has received documents from Scripts' co-conspirators, the record has gotten much worse for Scripts. In addition to the originally submitted evidence, Gilead summarizes below additional evidence, obtained after this Court granted the Asset Freeze Order, that further demonstrates that the Court should deny Scripts' motion to vacate the freeze.

II. Scripts Is a Willful Counterfeiter of HIV Medication with a Long History of Selling Counterfeits

Scripts was a willful counterfeiter of Gilead's medications continuously for at least the five years leading up to Gilead naming Scripts as a defendant and seizing over a thousand bottles of counterfeits at Scripts' warehouse. During this five-year run, **Scripts sold over 54,000 bottles of counterfeit Gilead-branded medication, every single one with a counterfeit pedigree.** Decl. of Susmitha Sunkara, dated Feb. 11, 2022 ("2/11/22 Sunkara Decl."), Dkt. No. 433 ¶ 7. **In other words, over the course of five years and $137 million in sales, Scripts has never sold a single legitimate Gilead medication**. And even when Scripts was directly informed that it was in fact selling counterfeits, Scripts simply sold off the counterfeits it had remaining in its inventory, and then moved on to the next counterfeit supplier. Scripts is not a long-running legitimate business: it is a long-running counterfeiting operation that finally got caught.

A. Scripts' Sales of Tens of Thousands of Counterfeits, With Fake Pills, Fake Labels, Fake Patient Instructional Outserts, and Fake Pedigrees

At the time Gilead obtained the Asset Freeze Order, Gilead knew Scripts had sold counterfeit Gilead-branded HIV medication that actually contained entirely different medication – high-dose prescription antipsychotics – in January 2020 and March 2021. See Dkt. No. 147 at

25-27. As set forth below, Gilead now knows that Scripts sold many additional counterfeit Gilead-branded HIV medications with the wrong tablets inside.

The sale of fake pills to patients suffering from HIV is unconscionable, but Scripts' counterfeiting does not stop there. When Gilead sells its HIV medication, it does not sell just tablets of medicine. It sells the tablets along with a custom and proprietary branded bottle, with branded labeling, branded patient instructions, and a branded pedigree. All of these elements are important for the safety and efficacy of the product, and all of them are mandated and regulated under federal law – after FDA approval, manufacturers cannot unilaterally change or omit any of them. Pharmacies who buy Gilead medication are buying the packaging, the instructions, and the pedigree as much as the tablets of medication themselves. Failing to include – or counterfeiting – any of those elements of the medication renders the product non-genuine and unsalable.

Gilead has proven that **every one** of the over 54,000 counterfeit Gilead-branded HIV medications that Scripts sold included, at minimum, a counterfeit pedigree that fraudulently lists a sale from Gilead that did not occur. 2/11/22 Sunkara Decl., Dkt. No. 433 ¶¶ 7-18. Gilead creates an authentic pedigree, bearing Gilead's trademarks, for every medication it sells, and relies on those pedigrees to maintain the security of its supply chain, to ensure counterfeits do not enter the stream of commerce, and to quickly track down and address potential safety issues, such as tampered-with or mishandled medications. *Id.* ¶¶ 5-6. Purchasers of Gilead-branded medications rely on pedigrees to confirm that they are buying authentic medication, sold by Gilead into its secure supply chain and in accordance with the medication's required standards for storage, handling, and shipping. Scripts' counterfeit pedigrees are part of the counterfeit manufacturing process: repackaging illicit product to trick purchasers into believing they are

receiving authentic product. Script's counterfeit pedigrees copy Gilead's well-known trademarks to imitate Gilead's authentic pedigrees and claim the medications were sold from Gilead in Gilead's secure supply stream, but they fraudulently list sales that never occurred.

Several hundred counterfeits seized from Scripts' warehouse had counterfeit patient Instructions for Use, or "outserts" – so called because they are folded and physically glued to the outside of the bottles – all of which copy Gilead's registered trademarks. Dkt. No. 457-11. This is another part of the counterfeit manufacturing process. These counterfeit Instructions for Use are unauthorized replicas that are printed on lower-quality paper than genuine Gilead outserts and tear easily upon opening; they contain formatting and spelling errors, including misspelling the active ingredients in the drug; and they have entire sections that are missing or illegible, such as entirely omitting drug interaction tables. 2/11/22 Sunkara Decl., Dkt. No. 433 ¶¶ 20-24. In addition to the hundreds of counterfeits that had counterfeit outserts, many of the bottles on Scripts' shelves had no outserts at all. *Id.*

Gilead also seized counterfeits from Scripts' warehouse that had non-authentic, counterfeit caps on the bottles to replace missing authentic caps. *Id.* ¶ 25. And as set forth below, Scripts sold counterfeits whose labels were damaged or sticky because the medication had been repurchased from patients on the street, and the previous patient labeling had to be removed and cleaned so the counterfeits could be resold with the appearance of being genuine.

B. Scripts' Prior Financing, Purchases, and Sales of Black-Market Counterfeit HIV Medication With Fake Pills in the Bottles

At the time Gilead obtained the Asset Freeze Order, Gilead's understanding was that the Scripts counterfeiting conspiracy started in 2019, and requested that the Seizure Order require Scripts to produce a list of all of its sales of purported Gilead-branded medication from 2019 to the date of the seizure. Dkt. No. 150. Evidence discovered since shows that Scripts'

involvement in counterfeiting was far more extensive than previously known. Gilead has learned that years earlier, from February 2017 to November 2018, Scripts willfully purchased another $34 million of "black market" counterfeit Gilead HIV medication from Mainspring Distribution LLC ("Mainspring"), a distributor whose principals have pled guilty and were sentenced in connection with the scheme. *See* Dkt. Nos. 431-1, 458–4. The Department of Justice has stated that this counterfeiting operation "specialized in expensive name-brand prescription drugs used to treat HIV, such as Atripla," a Gilead-branded HIV medication. Dkt. No. 457-1. According to the sworn testimony of the investigating FBI special agent, one Mainspring principal stated that his operation would "re-label bottles of drugs for something more expensive, or a bottle of drugs would contain 'candy' instead of medication." Dkt. No. 457-2 at ¶ 21.

1. Scripts Financed the Manufacture of the Black-Market Counterfeits With a $5 Million Advance That It Promptly Lost

Scripts in fact *financed* the creation of these black-market counterfeits. Scripts had a standing order with Mainspring to buy the counterfeit HIV medications, but the counterfeits were not coming fast enough. Dkt. No. 457-3 at ¶¶ 7-15. And so Scripts, through its owner Diamantstein, advanced an additional, approximately $5 million to Mainspring over the course of two months as prepayment for the counterfeits Mainspring was to supply. *Id.* Scripts and Mr. Diamantstein poured Scripts' financial resources into the counterfeiting scheme, financing the counterfeits by maxing out multiple credit cards to the point where Mr. Diamantstein's father had to co-sign another credit card. *Id.* at ¶ 10; *see also* Dkt. Nos. 457-4 – 457-7.

When Mainspring was caught and its principal was indicted, Scripts lost approximately $4.8 million of the "advance" it invested into this criminal enterprise. Dkt. No. 457-3 at ¶¶ 7-15.

2. Mr. Diamantstein Used His Father's Pharmacy to Funnel the Black-Market Counterfeits Into Scripts

Although Scripts' owner, Diamantstein, authorized the purchase and sale of these counterfeits and Scripts paid for them, on paper, Scripts claimed the counterfeits were sold to Lieb Pharmacy, the institution owned by Diamantstein's father and located downstairs from Scripts' warehouse, and that Lieb Pharmacy subsequently sold the product to Scripts. Dkt. No. 457-8; Dkt. No. 156 at ¶¶ 21, 23. Before this Court, Scripts has touted the alleged good name and long standing of Lieb Pharmacy, as though Scripts and Mr. Diamantstein should somehow be credited with Mr. Diamantstein's father's reputation. Dkt. No. 391 at p. 5. In reality, Scripts used Lieb Pharmacy's name and goodwill to conceal its purchase of over $34 million in black-market counterfeit Gilead-branded HIV medication. Scripts's modus operandi is to defraud patients and undermine the drug supply chain by using other well-respected trademarks to mask their counterfeit sales.

3. Scripts Continued to Sell the Black-Market Counterfeits After Learning About the Criminal Indictment

In addition to financing the manufacture of counterfeit HIV medication and funneling it through Diamantstein's father's pharmacy, Scripts has admitted that it learned about the of the indictment of Mainspring's principal no later than November 2018. Dkt. No. 457-9 at Interrogatory Response 4. And yet Scripts, knowing that it was buying fake HIV medication from a black-market criminal, continued for months to sell product labeled as Gilead-branded HIV medication it bought from that counterfeiter. Dkt. No. 457-8. In one of the ongoing litigations between Scripts and the counterfeiters, Diamantstein was questioned as to how he justified the sale of counterfeits after he learned about the indictment, and he testified: "**Well, I didn't know how much of that was illegal or not illegal… And at that point it's innocent until proven guilty, and I don't believe I had an obligation to let the drugs sit around**." Dkt.

No. 457-10 at 92:17-22. Actually, the DSCSA imposes an affirmative duty upon distributors to immediately quarantine even "suspect" products, including those with suspect pedigrees, and conduct an investigation. *See* 21 U.S.C. § 360eee-1(c)(4)(A); *see also id.* at § 361eee(21). But Diamantstein and Scripts continued to pour these dangerous counterfeit HIV medications into the pharmaceutical supply chain, and continued reaping illicit profits at the expense of patients. And once its supply of counterfeits from Mainspring finally ran out, Scripts pivoted and started sourcing (and helping manufacture) counterfeits from the already-named Defendants in this action.

C. Scripts Continues to Sell Counterfeits After Being Repeatedly Informed that Its Suppliers Are Counterfeiters

Scripts' dealings with the "black-market" counterfeiter Mainspring is just the first of several times that Scripts knowingly continued to sell counterfeits **after** being directly informed that its supplier was providing HIV medication with the wrong pills inside the bottle.

For example, in June 2021, Gilead itself approached Scripts with evidence that Scripts had sold counterfeit Gilead-branded medications with the wrong pills inside the bottle and fraudulent pedigrees. Scripts' response was to claim surprise, deny responsibility, and refuse to provide further information: "Scripts had no reason to believe that the documents were falsified and that the [Gilead] products had been altered. Prior to these purchases, Gentek had been a reliable and credible vendor." Dkt. No. 421-5 (emphasis added). In reality, Gilead now knows, over six months prior, the FDA's Office of Criminal Investigation had informed Scripts that Scripts was selling counterfeit bottles of SYMTUZA® (an HIV drug made by Janssen Pharmaceuticals) that had the wrong pills inside the bottle, which Scripts confirmed it purchased from Supplier Defendant Gentek. *See* Dkt. No. 421-2. Scripts' reaction to learning, directly from the FDA's mouth, that it was selling counterfeits with the wrong pills inside was to quickly

sell off all remaining Gentek-supplied bottles they had in stock, including Gilead-branded HIV medication, and then later lie to Gilead about it. *See* Dkt. No. 443-7; *see also* Waters Decl. Exhibit 84 (pedigrees showing sale of Gentek product after FDA email).

Scripts' emails further show that on February 8, 2021 the FDA Office of Criminal Investigation identified *another* one of Scripts' counterfeit suppliers, Abacus Distributors ("Abacus"), as suspect. Clearly alarmed, Scripts pushed back, writing: "Why has your investigation now morphed into another supplier and customer of Scripts?" Dkt. No. 421-3. The FDA responded: "Our job is to determine breaches in the supply chain. Investigative research has led us to another supplier" – *i.e.*, Abacus. *Id.* True to form, **within two days of the FDA Office of Criminal Investigation identifying Abacus as a suspect, Scripts had sold all of its remaining stock of counterfeit Gilead-branded medication from Abacus to a retail pharmacy, clearing out its warehouse of some 370 bottles, and ensuring that those counterfeits would end up in the hands of hundreds of patients, and not the FDA.** *See* Dkt. No. 443-8. Also true to form, knowing the FDA was on to Abacus, Scripts abruptly stopped buying from Abacus and moved on to purchase from other counterfeit suppliers. *Id.*

D. Mr. Diamantstein Personally Helped Manufacture Counterfeits by Dictating the Contents of Counterfeit Pedigrees, and Worked Directly With Street-Level Collectors to Clean Bottles Purchased from Patients

As Gilead has set forth in prior briefings, Collector Defendants Boris Abramov and Daniel Gelbinovich helped manufacture the counterfeits by supervising a team that bought bottles of HIV medication (empty or full) from patients on the street, "cleaned" the bottles to remove patient labeling, and created counterfeit pedigrees. *See* Dkt. No. 607 at 81–86. Gilead now knows that Scripts, and Diamantstein personally, worked directly with the Collector Defendants to manufacture the counterfeits, including repackaging the illicit street-purchased bottles by having them stripped of their patient labeling, cleaned to resemble authentic product,

and creating fraudulent pedigrees for each bottle so that the counterfeits could be sold back into the legitimate supply chain and dispensed to an unsuspecting patient.

Seized text messages show that Collector Defendant Abramov alone visited Scripts at least seven times in 2021.[1] Although Scripts was careful to keep these meetings in-person only, with no written record, Abramov wrote contemporaneous texts to his boss, Gelbinovich, recording what Scripts was orally instructing him to do. For example, during one on-site visit to Scripts, Abramov texted back to Gelbinovich: "**There is gonna be a lot of editing [to the pedigrees] so it'll take me sometime**…. **Bro he's asking me to take off the closed pharmacy on the pedigree**. **He wants abc to rxwholesale to scripts. . . . But how are we supposed to write that.**" Dkt. No. 608-133 (emphasis added). Although Abramov's text does not directly name who at Scripts was giving him these instructions he does say, "I'm with his guys in his office." *Id.* The only person at Scripts who could feasibly be referred to as having "his guys" in "his office" is Scripts' owner and president, Diamantstein. *Id.*

This text leaves no doubt that Scripts and Diamantstein were part of the counterfeit manufacturing process, ordering the creation of counterfeit pedigrees and dictating the fraudulent data to be included on them. In instructing that the pedigree should say the bottle was sold from "abc to rxwholesale to scripts," Scripts was creating a counterfeit pedigree that falsely showed Gelbinovich's company purchasing directly from a Gilead-authorized distributor – AmerisourceBergen Corp., commonly abbreviated as ABC – and then selling directly to Scripts.

---

[1] Text messages show that Abramov visited Scripts on June 23, Waters Decl. Ex. 75; June 24, Dkt. No. 608-128; July 12, Waters Decl. Ex. 76; July 15, Waters Decl. Ex. 77; July 20, Waters Decl. Ex. 78; July 22, Waters Decl. Ex. 79; and July 29, Dkt. No. 608-128.

Diamantstein also worked directly with Gelbinovich, the boss of the collectors. On March 23, 2021, Diamantstein texted Gelbinovich an image of a falsified pedigree to use as a template and stated, "This is an example." Waters Decl. Ex. 80. That same day, Gelbinovich texted Abramov that Diamantstein was "going through it by lot number(s)" – meaning that he was working on creating falsified pedigrees—and that it might take "a few hours." Waters Decl. Ex. 81.

Gelbinovich also received complaints from Scripts about the quality of the counterfeits he was creating from bottles repurchased from patients. In a voicemail, Gelbinovich reported to Abramov that his "buyers," – i.e., Scripts – instructed him to make sure the counterfeit medications were "handled better, like no sticky stuff [from the removal of patient labeling], et cetera, et cetera" to mask their illicit origin. Dkt. No. 608-132.

Finally, Scripts was also directly involved in instructing the Collector Defendants which Gilead-branded medications to buy from patients so they could be resold as counterfeits. During a different visit to Scripts, Abramov texted Gelbinovich: "I'll see soon, let me finish here at scripts. lots to do." Dkt. No. 608-128. A few hours later, Abramov texted a picture of a shelf full of loose bottles of purported TRUVADA, a Gilead HIV medication, from the Scripts warehouse:

Id. Seeing the full stock of purported TRUVADA at Scripts, Mr. Gelbinovich texted back: "OK, so no Truvada?" – meaning they should forego buying more of that that particular medication back from patients. *Id.* Mr. Abramov responded, "**I'm gonna ask scripts** but my opinion is it won't move." *Id.* (emphasis added).

E. Scripts Had a Safe Full of Cash and Prepaid Credit Cards at Its Warehouse

During the course of the seizure, Gilead discovered a safe in Scripts' warehouse that contained approximately $100,000 cash stacked in bills of various denominations, as well as stacks of envelopes containing over 150 prepaid American Express cards with balances varying between $25 and $3,000, totaling approximately another $100,000.

Dkt. No. 434 ¶ 3. Scripts does not accept payment from its customers in cash, and legitimate pharmaceutical wholesalers do not maintain these types of untraceable funds in a locked safe in the warehouse. Given Scripts' close collaboration with the Collector Defendants buying bottles from patients on the street, the evidence shows that Scripts was using this safe full of cash and untraceable pre-paid cards to finance those street-level purchases.

F. Scripts Purchased the Counterfeits by Maxing Out a Rotating Series of Credit Cards

As noted above, Scripts financed Mainspring's manufacture of the counterfeits by paying millions of dollars to Mainspring in advance, and used credit cards to make those payments. Dkt. No. 457-3 at ¶¶ 7-15 & 457-4 – 457-7. After Mainspring's principals were indicted and Scripts was forced to find new counterfeit suppliers, Scripts continued to use a rotating series of continually maxed-out credits cards to purchase at least a large portion of $130 million-plus in counterfeit Gilead-branded medication it trafficked, and scrambled to make minimum payments due on those credit cards. Dkt. No. 432-1; Dkt. No. 457-3 at ¶ 10; Dkt. Nos. 457-4 – 457-7; Waters Decl. Exs. 82, 83, 85.

This constant rotation of credit cards left Scripts with a shortage of funds to pay its suppliers co-conspirators. For example, in May 2021, Diamantstein wrote to Leader Defendant Dunn: "You deposited the ITC check ??" – i.e., the check Scripts had written to pay Supplier Defendant ITC for counterfeits. Dkt. No. 608-30. When Leader Defendant Dunn confirmed that he had deposited the check, Diamantstein wrote, "We were not ready for the deposit" – i.e., Scripts did not have the cash on hand to cover the check. *Id.* Mr. Diamantstein then instructed his employees to "push" to get payments from two pharmacy customers to cover the funds. *Id.* And in a different series of texts, Leader Defendant Ralhan upbraided Mr. Diamantstein for failing to make payments on the counterfeits, saying that Mr. Ralhan had to "front" additional

funds to a representative "to keep her on track as she was getting a little anxious." Waters Decl. Ex. 83. Diamantstein represented that Scripts only had $300,000 in funds available, and hoped to get in an additional $260,000 from a pharmacy in coming days. *Id.* Mr. Ralhan demanded that Scripts pay the $300,000 it had available immediately, but Scripts agrees only to pay $150,000 to "calm things down." *Id.*; *see also* Dkt. No. 457-4 (Mr. Diamantstein writing to the principal of the counterfeiter Mainspring: "my dad had to co sign on my car hahahahaha").

III. ARGUMENT

As stated above, the Court should hold that Scripts bears the burden of proof in moving to amend the preliminary injunction Asset Freeze Order, and so reject Scripts' attempt to reargue *de novo* the law and facts. Nevertheless, Scripts' arguments fail for the following reasons.

A. Gilead Is More than Likely to Succeed on Its Claims

Instead of legitimately disputing the criminal counterfeiting scheme alleged in the Complaint, Scripts devotes the majority of its brief to arguing that Gilead's claims fail as a matter of law. Scripts' arguments are meritless.

1. The Medication Sold by Scripts Is Infringing for Many Reasons In Addition to the Counterfeit Pedigrees

All of Scripts' arguments concerning the strength of Gilead's claims are directed toward the fact that every bottle Scripts sold had a counterfeit pedigree. Even if the Court were to reach Scripts' legal arguments despite Scripts' failure to meet its burden of proof, it would be unnecessary to review Scripts' arguments concerning the counterfeit pedigrees, because the counterfeit pedigrees are only one of several reasons why the Gilead-branded product sold by Scripts violated the Lanham Act. Indeed, when the Court granted the Asset Freeze Order, Gilead did not know or present evidence that all of Scripts' pedigrees were counterfeits: that is *additional* evidence, beyond what Gilead presented in its initial application, that further supports

the freeze. Putting the counterfeit pedigrees to one side, any one of the additional theories of liability Gilead has pled in this case is more than sufficient to find Gilead likely to succeed on its claims.

First, it is undisputed that Scripts sold Gilead-branded bottles of medications with the wrong pills inside, and it is undisputed that those are, of course, counterfeits within the meaning of the Lanham Act. In fact, as described above, Scripts began its counterfeiting career by buying intentionally adulterated Gilead-branded medications from black-market criminals who sold bottles that either had the wrong medication inside, or contained entirely fake pills. Dkt. No. 458-4; Dkt. No. 457-1.

Second, as set forth above, several hundred products seized from Scripts' warehouse had counterfeit patient Instructions for Use, or "outserts," glued to the bottles, all bearing Gilead's trademarks. *See supra*, pp. 14-15. These poor-quality, unauthorized and inauthentic copies of Gilead's instructional outserts unambiguously render the products counterfeit under the Lanham Act. *Johnson & Johnson Wholesale Inc. v. South Pointe*, 2014 WL 12558573 at *12 (E.D.N.Y. Mar. 28, 2014) (finding defendants liable for counterfeiting where they sold medical devices with "counterfeit inserts" printed on different paper than plaintiff's authentic instructional inserts). In its Motion, Scripts offers only the following response to Gilead's previously submitted evidence concerning counterfeits with counterfeit outserts, buried at the end of its introductory section: "Gilead has absolutely no direct evidence that any of the medications actually sold by Scripts had an incorrect outsert." Dkt. No. 1006 ("Br.") at 2. That half-hearted argument borders on frivolous. Gilead of course does not have possession of the counterfeits that Scripts sold and were already dispensed to patients, but Gilead seized several hundred products bearing Gilead's trademarks with counterfeit outserts that were sitting in Scripts'

warehouse, ready to be sold to customers. The only reason Scripts did not sell those counterfeits to pharmacies is that Gilead seized them. It is undisputed that those hundreds of outserts were fake reproductions of authentic Gilead outserts, and it is undisputed that products bearing those fake outserts are counterfeits within the meaning of the Lanham Act.

Third, Gilead has also asserted trademark infringement claims based on the material-differences doctrine.[2] Briefly stated, the doctrine provides that if a distributor sells a version of product or its packaging that is "materially different" from the product as it is sold by the manufacturer in the United States, the product is no longer considered authentic and its sale is an act of trademark infringement – even if it bears the original trademarks applied by the manufacturer and there is no alteration of the product inside the packaging. *See, e.g.*, *Zino Davidoff SA v. CVS Corp.*, 571 F.3d 238, 243-246 (2d Cir. 2009). Courts "apply a low threshold of materiality, requiring no more than a slight difference" to find a product materially different. *Id.* Gilead sells authentic Gilead-branded medication with authentic pedigrees that accurately provide details of Gilead's sale of the product, with authentic outserts affixed to the bottle. Scripts sold medication bearing Gilead trademarks with fake pills inside, pedigrees listing fraudulent sales that Gilead never made; fake outserts or no outserts at all; fake bottle caps; and labels that were damaged because they were repurchased from patients and the patient label applied by the pharmacy had to be removed. *See* Dkt. No. 456 at 13–15, 2/11/22 Sunkara Decl.,

[2] In its original motion, Scripts asserted that only counterfeiting claims, and not other infringement claims, can give rise to an asset freeze under the Lanham Act. As Gilead pointed out in opposition, that is incorrect. *See, e.g.*, *Gianni Versace, S.p.A. v. Awada*, 95 F. App'x 224, 225 (9th Cir. 2004); *Juul Labs, Inc. v. 4X PODS*, 509 F. Supp. 3d 52, 71 (D.N.J. 2020). This time around, Scripts appears to have abandoned its position that straight infringement claims cannot support an asset freeze.

Dkt. No. 433 ¶¶ 7-18. These are all unquestionably "material differences" that render the bottles infringing.

Moreover, authentic pedigrees are a quality-control and anti-counterfeiting tool used by Gilead to help protect the safety of its products and the integrity of its supply chain. 2/11/22 Sunkara Decl., Dkt. No. 433 ¶¶ 5-6. The sale of bottles with fraudulent pedigrees that contain completely false sales histories undermines Gilead quality-control efforts, which also renders the bottles infringing. *See Zino Davidoff*, 571 F.3d 238 at 244 (finding sales that could interfere with a manufacturer's ability to issue a targeted recall render the product infringing, even where the manufacturer had never before issued such a recall). The harm to public health created by Scripts' undermining of the U.S. drug supply chain and drug quality-control procedures further justifies the imposition of the extraordinary injunctive relief this Court has granted.

B. Every Bottle Sold by Scripts With a Counterfeit Pedigree Is Counterfeit

Pedigrees are a critical component of the pharmaceutical products that Gilead sells. Pedigrees allow every entity that sells a Gilead-branded medication, down to the pharmacy that dispenses to a patient, to have confidence that they are holding an authentic product manufactured by Gilead and sold through a secure supply chain. Pedigrees are how pharmacists determine that the Gilead-branded medication they are about to dispense is authentic: the alternative is to open the bottle, puncture the seal, and chemically test the pills, which renders the medication unusable. Counterfeit pedigrees contain fraudulent information intended to trick purchasers and dispensers into believing they have authentic medication that went through a secure supply chain, when in fact the opposite is true. Counterfeit pedigrees are a critical and necessary part of the counterfeit manufacturing process.

Every pedigree for **every** bottle of medication bearing Gilead trademarks that Scripts has ever sold, beginning in 2017, is a fake, invented out of whole cloth. Each fake pedigree

reproduces Gilead's registered trademarks without authorization and fraudulently misrepresents the origin of the medication. Fake pedigrees fall squarely within the statutory definition of "counterfeit." Scripts nevertheless argues that the fake pedigrees are irrelevant, because the only thing that matters under the Lanham Act is whether the tablets inside the bottle are, as Scripts calls them, "genuine." Scripts is mistaken. Courts in this District and elsewhere regularly find once-genuine products to be counterfeits when they are sold with counterfeit marks on, for example, the packaging, advertising, or instructions.

1. The Fake Pedigrees Meet the Statutory Definition of Counterfeit

The Lanham Act defines a "counterfeit" as a "spurious mark which is identical with, or substantially indistinguishable from a registered mark." 15 U.S.C. § 1127. The Lanham Act does not define a "spurious" mark, but courts in this Circuit have looked to the Black's Law Dictionary definition: "Deceptively suggesting an erroneous origin; fake." *See Excelled Sheepskin & Leather Coat Corp. v. Oregon Brewing Co.*, 2015 WL 4468083, at *3 (S.D.N.Y. July 8, 2015) (collecting cases), *rev'd in part on other grounds, vacated in part on other grounds,* 897 F.3d 413 (2d Cir. 2018). Under the Lanham Act, defendants are liable for any "use in commerce" of any "counterfeit … of a registered mark", including any use "in connection with the sale, offering for sale, distribution, or advertising of any goods or service." 15 U.S.C. § 1114(1)(a); *see id.* § 1117(b).

Authentic Gilead-branded medication includes a Gilead-created and -issued pedigree. 2/11/22 Sunkara Decl., Dkt. No. 433, ¶ 5. Every Gilead authentic pedigree contains at least two registered word marks, in plain text: "Gilead" and the brand name of the medication (*e.g.*, BIKTARVY®). Gilead's authentic pedigrees also list the details of the medication's initial sale, such as the date of the transaction, Gilead's invoice number and the name and address of the authorized distributor who purchased it. 2/11/22 Sunkara Decl. ¶ 5. Every time that medication

is subsequently sold, the downstream sellers are required to continue the chain of custody on the pedigree by copying exactly what Gilead (and any other upstream sellers) included in the transaction information, and then adding their own sales transaction to the list. *Id.* ¶¶ 5-6. This means that the bottle of medication is accompanied at every step with an authentic pedigree, bearing the registered Gilead marks as Gilead originally applied them, that accurately lists the chain of custody for the medication.

Scripts' pedigrees, in contrast, are proven fakes. *Id.* ¶ 7. Gilead's authentic pedigrees accurately list the details of Gilead's original sale of the bottle to an authorized distributor; Scripts' counterfeit pedigrees show a fraudulent transaction that never occurred. *Id.* ¶¶ 7-14,16-17. They are fabricated with the intent of tricking purchasers into trusting that the medication has been distributed through authorized and secure channels and is therefore genuine.

Scripts' fake pedigrees therefore fall squarely within the Lanham Act's definition of a counterfeit. The marks on these fake pedigrees are quintessentially "spurious": the entire purpose of the marks is to "deceptively suggest an erroneous origin"—*i.e.*, to make fraudulent misrepresentations about the source of the product. *Excelled Sheepskin*, 2015 WL 4468083, at *3. And because Scripts' counterfeit pedigrees accompanied *every* sale of *every* bottle, they unquestionably were "used in connection with the sale [or] distribution" of the product under 15 U.S.C. § 1114(1)(a). In sum, Scripts' fake pedigrees (1) exactly copy Gilead's registered marks (2) on a fake document without Gilead's permission (3) in order to misrepresent the medication's origin (4) in connection with the sale and distribution of the medication. They are, definitionally, counterfeits under the Lanham Act.

2. The Use of Counterfeit Pedigrees to Sell Allegedly "Authentic" Product Is an Act of Counterfeiting

In its brief, Scripts argues that the Lanham Act imposes a bright-line rule: if the product itself is supposedly "genuine" or "authentic," there can be no claim for counterfeiting, no matter how many counterfeit marks are used to advertise, sell, and distribute that "genuine" product. Dkt. No. 1006 at 12. Scripts further warns that finding its fake pedigrees to be counterfeits would stretch the Lanham Act well beyond the bounds of the existing case law, and claims that "[i]t is exceptionally rare for a court to even entertain a claim of counterfeiting where the product itself is genuine." *Id.*

Not so. Several courts, including within this District, have found defendants liable for counterfeiting under the Lanham Act under the same factual circumstances presented here: the defendant sells what it claims to be the plaintiff's "genuine" product, but uses counterfeits of the plaintiffs' registered marks in order to do so. Courts routinely find that by using counterfeit marks, defendants conceal that the product is being distributed outside of the plaintiffs' authorized channels, frustrating the plaintiffs' quality-control efforts and causing confusion as to the origin of the product. Under these circumstances, courts reject defendants' arguments that they are simply reselling plaintiffs' authentic goods and find them liable for counterfeiting.

For example, in *State of Idaho Potato Comm'n v. G & T Terminal Packaging, Inc.*, 425 F.3d 708 (9th Cir. 2005), the defendant originally had a license to use plaintiff's marks to sell its products, but continued to make unauthorized use of those marks when the license expired. *Id.* at 711-12. The defendant argued it could not be held liable for counterfeiting because it was continuing to sell the same authentic product that it had sold while the license was still active, and so its unauthorized use of plaintiff's mark was not spurious or confusing. *Id.* at 721. The Ninth Circuit rejected that argument and affirmed an award of statutory damages for willful

counterfeiting. *Id.* The court held that by putting the plaintiff's marks on its packaging, the defendant implied that its products were being "distributed in accordance with [plaintiff's] procedures, and the fact this was not the case was likely to cause consumer confusion." *Id.* at 722. Citing Second Circuit caselaw, the court reasoned that because the unauthorized use of plaintiff's marks interfered with the plaintiff's quality-control measures, including the chain of distribution, the use of plaintiff's trademark constituted counterfeiting, even if there was no actual difference in the products themselves. *Id.* (quoting *El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392, 395 (2d Cir. 1986) ("The actual quality of the goods is irrelevant; it is the control of quality that a trademark holder is entitled to maintain.")).

Similarly, in *Monsanto Co. v. Haskel Trading, Inc.*, 13 F. Supp. 2d 349 (E.D.N.Y. 1998), the defendants repackaged the plaintiff's products into counterfeit boxes. *Id.* at 352. The defendants emphasized that their counterfeit boxes contained non-counterfeit product, and that the boxes correctly identified the plaintiff as the manufacturer of the product. *Id.* They therefore argued their use of plaintiff's marks on the boxes could not cause confusion as to origin and did not constitute counterfeiting under the Lanham Act. *Id.* at 356. In rejecting that argument, the Court noted that the genuine boxes for plaintiff's product "serve several important functions," including that they allowed plaintiff "to track the manufacture and packing of the product" and "are designed to expedite recalls in the event of any problems with the health, safety, or freshness of food products." *Id.* at 357. The court thus held that the counterfeit boxes were likely to cause confusion as to origin, and held that the repackaged products were counterfeits within the meaning of the Lanham Act. *Id.*; *see also Monsanto Co. v. Campuzano*, 206 F. Supp. 2d 1239 (S.D. Fla. 2002) (reaching the same conclusion with regard to a similar scheme), *order modified on other grounds*, 206 F. Supp.2d 1270 (S.D. Fla. 2002).

Next, in *Johnson & Johnson,* 2014 WL 12558573, the defendants claimed they were selling the plaintiff's authentic medical devices, but sold them in counterfeit boxes with counterfeit instructional inserts. *Id.* at *2. The products had originally been purchased overseas, and in order to conceal the devices' international origin, the products were repacked into the counterfeit boxes with counterfeit inserts that replicated authentic U.S. boxes and U.S. inserts. *Id.* The court readily held that the counterfeit packaging and inserts caused confusion as to the origin of the products, and granted summary judgment as to liability for counterfeiting under the Lanham Act. *Id.* at **12-14.

Finally, in *Coty Inc. v. Cosmopolitan Cosmetics Inc.*, 432 F. Supp. 3d 345 (S.D.N.Y. 2020), the defendant sold bottles of perfume that the plaintiff had manufactured, bearing the plaintiff's registered marks as applied by the plaintiff. But while the perfume itself was unaltered, the products sold by the defendants had the "Production Codes" on the bottle removed, obscured, or stickered over. *Id.* at 349. The plaintiff alleged that those production codes were "quality assurance, anti-counterfeiting and anti-theft measure[s]" that "facilitate[] corrective action or targeted recalls." *Id*. The purpose of the defendants' obscuring the production codes on the bottles was "to conceal the identity of the seller who is diverting the products outside of authorized distribution channels." *Id.* Rejecting the defendants' argument that they were merely reselling the plaintiff's authentic product, the court held:

> Plaintiffs have alleged the Decoded Products bear Plaintiffs' registered trademark, are not authorized for resale, and are sold in an "intentionally fraudulent" manner by which to trick consumers into believing they are the "genuine article" despite the material difference [i.e., the obscuring of the production code and the consequent interference with plaintiffs' quality-control measures]. Plaintiffs have alleged a plausible counterfeiting claim.

Id. at 353.

Here, as in the cases cited above, Scripts sold medications by making unauthorized use of the Gilead's registered marks to fraudulently conceal that the products had actually been sold outside of Gilead's authorized distribution channels. And like the plaintiffs in those cases, Gilead unquestionably uses authentic pedigrees as part of its quality-control and anti-counterfeiting efforts, primarily for the purpose of ensuring the efficacy of its medicines and the safety of the patients that take them. 2/11/22 Sunkara Decl., Dkt. No. 433 ¶ 4. Thus, under this well-established line of case law, it cannot reasonably be questioned that the sale of medication with counterfeit pedigrees is actionable counterfeiting under the Lanham Act.

While Scripts' liability for selling counterfeits is well-established, the facts of this case are an extreme outlier in the anti-counterfeiting caselaw in terms of the egregiousness of the counterfeiting and the injury to public health. Scripts' counterfeits were manufactured from medications that were taken away from needy HIV patients on the street, manufactured into counterfeits using fraudulent pedigrees that intentionally lie about the product's origin, and were sold through fly-by-night counterfeit suppliers after being stored and handled in unknown and potentially unsafe conditions by criminals putting illicit profits over patient safety. As Congress recognized in passing the DSCSA, maintaining a secure and traceable supply chain for pharmaceuticals is absolutely crucial to combatting counterfeits and ensuring patient safety. *Cf. Shenzhen Smoore Tech. Ltd. v. Anuonuo Int'l Trade Co.*, 2020 WL 7390518, at *9 (S.D.N.Y. Oct. 23, 2020) ("Moreover, it bears noting that the products at issue here are electronic cigarette products, which undeniably implicate health concerns. The consequences of purchasing and using a counterfeit vape product over which the trademark owner does not have quality control has considerably more potential to cause harm than purchase and use of a defective counterfeit

watch or stuffed animal."). There can be no doubt that the fake pedigrees at issue are intended to cause confusion and trick purchasers about the illicit origin of the product.

3. Scripts' Cited Authority Is Inapposite

Against this backdrop, Scripts is simply incorrect that it is impossible for a defendant to engage in counterfeiting if it sells an allegedly "genuine" product, regardless of the counterfeit marks it uses in connection with those sales. Scripts cites *United States v. Hanafy*, 302 F.3d 485 (5th Cir. 2002) for the proposition that selling allegedly "authentic" goods in counterfeit cardboard trays does not constitute counterfeiting under the Lanham Act. But *Hanafy* was a criminal action, not a Lanham Act case. *Id.* at 486-87. In finding that the use of counterfeit cardboard trays did not violate the criminal counterfeiting statute, 18 U.S.C. § 2320, the *Hanafy* Court specifically noted that its inquiry was different from that of a civil case, and noted that in the civil context, courts had reached the opposite conclusion – and cited as an example the *Monsanto* case from this District, discussed above. *Id.* at 488-489. *Hanafy* is therefore entirely inapposite.

Also inapposite is the legislative history that Scripts cites, which concerns the distinction between counterfeits and "gray market goods" – *i.e.*, overseas product reimported into the United States and sold in competition with U.S. product. Br. at 15. This is not a gray-goods case, and Scripts is not alleged to have sold bottles packaged for international markets.

C. Gilead's Claims are Not Precluded

Finally, Scripts argues, relying on *Amarin Pharma, Inc. v ITC*, 923 F. 3d. 959 (Fed. Cir. 2019), that the DSCSA precludes Gilead's Lanham Act claims. But the Supreme Court has ruled that the Lanham Act is not precluded by federal law, even where the Lanham Act claim raises issues that are highly regulated by the FDA. *Pom Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014). The *Amarin* court's finding of preclusion was a narrow exception to *Pom Wonderful* —

as the *Amarin* court itself recognized. 923 F.3d at 969. There, the plaintiff directly alleged that the defendants' advertising was false *because* it violated FDA regulations. *Id.* at 967-970. Since the plaintiff's claims were "based solely on alleged violations of the FDCA" and the plaintiff alleged no independent basis that the advertising was false under the Lanham Act, they were precluded. *Id.* at 969.

Here, Gilead's allegations that Scripts sold counterfeits with various counterfeit elements, including fake pedigrees, stand fully on their own, without any reference to whether the pedigrees also violate the DSCSA. Gilead's authentic pedigree listed the actual details of a sale; the counterfeit pedigrees list fraudulent details of a sale that never actually occurred. The falsity of the statements on the fake pedigrees is a matter of simple fact, not FDA regulation. *Pom Wonderful* squarely forecloses Scripts' argument that the FDA's regulation of pedigrees strips manufacturers' ability to protect and enforce their trademark rights. That Scripts' actions violate the Lanham Act *and* also violates a host of federal regulatory and criminal statutes is not an exculpatory fact.

The post-*Pom Wonderful* district court cases cited by Scripts only serve to prove Gilead's point. *See Methods Pharm., LLC v. H-2 Pharma, LLC*, 2022 U.S. Dist. LEXIS 19541 (M.D. Ala. Feb. 3, 2022); *Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323 (N.D. Ga. 2016); *JHP Pharm., Ltd. Liab. Co. v. Hospira, Inc.*, 52 F. Supp. 3d 992 (C.D. Cal. 2014). In each case, the Court refused to find Lanham Act claims for prescription drugs precluded. For example, *JHP Pharms.* held that with regard to prescription drugs, *Pom Wonderful* establishes "a general presumption in favor of Lanham Act claims and against preclusion," and that *Pom Wonderful* made "abundantly clear [that] where the court is not called upon to make determinations within the exclusive purview of FDA authority, a Lanham Act claim may be

heard, even if the subject of the claim touches the area of authority of the FDCA." *Id.* at 1000, 1004. The *JHP* court thus rejected the argument that Lanham Act false advertising claims were precluded based on the allegation that the competitor had falsely implied its product was "FDA-approved." *Id.* at 1004. It is of course true that only the FDA can cause a drug to be FDA-approved, but the factual question of whether or not the FDA had granted such approval was easily determined, and "the Court need not refer the question to the FDA's expertise to make factual determinations." *Id.* at 1002.

Similarly, in *Methods Pharms.*, the plaintiff alleged that the defendant falsely marketed its drug product as being serialized, and defendant contended that Lanham Act claim was precluded, arguing that serialization requirements are propounded by the FDA, and only the FDA can enforce those requirements; the court rejected that argument: "[Plaintiff] asserts that [defendant] affirmatively *represents* that its products are serialized when they *in fact are not*. The veracity of those two facts is wholly independent of any collateral consideration of whether the FDA *requires* serialization for H-2's products. The Court is well equipped to parse the truth of those assertions without any resort to FDA regulations." *Id.* at *14. Here, the only factual determination the Court needs to make with regard to pedigrees bearing Gilead's trademarks and proclaiming sales by Gilead is whether or not they list fake sales that never occurred – facts that are in Gilead's possession, not the FDA's.

Finally, Scripts makes a last-ditch argument that the DSCSA offers distributors a choice with regard to how to prepare a pedigree, and that "Gilead's counterfeiting claims under the Lanham Act would take that choice away." Br. at 8. But the DSCSA does not provide distributors with the "choice" of listing either a real sales history or an entirely made-up one.

The only option Gilead's counterfeiting claims take away is the option to sell prescription drugs with a pedigree that fraudulently lists transactions that never occurred.

D. The Counterfeit Pedigrees Are Used in Commerce

Scripts argues that the fake pedigrees cannot be counterfeits under the Lanham Act because they do not satisfy the "use in commerce" requirement for trademark infringement because they are not physically attached to the product. Scripts is incorrect.

Scripts relies primarily on case law involving trademark *registration*, not trademark *infringement*.[3] The trademark registration statute, 15 U.S.C. § 1051, provides that in order to register a mark the applicant must demonstrate that the mark is "in use in commerce." *Id.* § 1051(a)(3)(C). For purposes of trademark registration, the phrase "use in commerce" is defined by 15 U.S.C § 1127, which requires that applicant make "*bona fide* use of a mark in the ordinary course of the trade, and not made merely to reserve a right in the mark," and also requires that the mark be "placed in any manner on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto."

But this case involves questions of trademark infringement, not trademark registration. The trademark infringement statute, 15 U.S.C. § 1114(a), provides a cause of action for infringement against a person who, without consent, shall "use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive." Despite this broad language, Scripts argues that the narrow Section 1127 definition of "use in commerce," which applies to

---

[3] *EST Inc. v. Royal-Grow Prods., LLC*, 526 F. Supp. 3d 943 (D. Kan. 2021); *In re Bright of Am., Inc.*, 1979 TTAB LEXIS 100, *5 (Trademark Trial & App. Bd. 1979); *In re Chi. Rawhide Mfg. Co.*, 59 C.C.P.A. 963, 455 F.2d 563, 564-65 (C.C.P.A. 1972)

trademark *registration*, applies with equal force to claims for trademark *infringement* under Section 1114(a).

Scripts cites only two infringement cases in support of this argument. The first case, *Versatop*, was **reversed** on appeal years ago – and was reversed on precisely the "use in commerce" point for which Scripts cites the case. *VersaTop Support Sys., LLC v. Ga. Expo, Inc.*, 921 F.3d 1364, 1370 (Fed. Cir. 2019). The second case, *Kische USA, LLC vs. Simsek*, 2017 U.S. Dist. LEXIS 196191 (W.D. Wash. 2017), was decided before the Federal Circuit's decision in *Versatop*, and relies entirely on the now-overruled *Versatop* district court. Simply put, Scripts relies on bad case law. [4]

As the Federal Circuit held in reversing the authority upon which Scripts relies: "the district court in this case incorrectly applied the definition of 'use in commerce' that is included in the statute for purposes of trademark registration. This definition does not apply to trademark infringement." *Versatop*, 921 F. 3d at 1370. The Federal Circuit went on to collect various authorities, including the Second Circuit and *McCarthy on Trademarks*, rejecting the precise argument Scripts advances here: namely, that the Section 1127 "use in commerce" requirement for trademark registration applies equally to claims for trademark infringement under 15 U.S.C. § 1114(a). *Id.* at 1369-1371 (citing *Rescuecom Corp. v. Google Inc.,* 562 F.3d 123, 127 (2d Cir. 2009) and 4 McCarthy 23:11.50 (5th ed. 2018)).

---

[4] Scripts' authority is distinguishable for a number of other reasons as well. All Scripts' cited cases involve fact patterns where there were no registered marks at all on the product or its packaging; here, Gilead's marks are on the product, the bottle, the affixed outserts, and the pedigrees. Moreover, Scripts relies on cases involving invoices or receipts, created by the seller, for a particular sale. Pedigrees are a far cry from a receipt or invoice: they are government-mandated anti-counterfeiting measures that by law originate with the manufacturer and must accompany the product with every subsequent sale.

In the infringement context, the "use in commerce" standard is "broad and has a sweeping reach." *LoanStreet, Inc. v. Troia*, 21 CIV. 6166 (NRB), 2022 WL 3544170, at *10 (S.D.N.Y. Aug. 17, 2022) (collecting cases). Thus, New York federal courts have found, for purposes of infringement under Section 1114(a), that a defendant made "use in commerce" of a plaintiff's trademarks by: using those marks in online advertising and in its Twitter profile, *Trane Intl. Inc. v. Calentadores de Am., S.A. de C.V.*, 21-CV-4497 (DLC), 2022 WL 1523527, at *1, 4 (S.D.N.Y. May 13, 2022)); using plaintiff's marks in a store display and at a trade show, *Elastic Wonder, Inc. v. Posey*, 13-CV-5603 (JGK), 2015 WL 273691, at *3 (S.D.N.Y. Jan. 22, 2015); and in "pitching" a magazine whose title would use the plaintiff's mark, even where the defendant did not create a physical "mock-up or protype" bearing the physical mark, *AARP v. 200 Kelsey Associates, LLC*, 06-CV-81 (SCR), 2009 WL 47499, at *11–12 (S.D.N.Y. Jan. 8, 2009). The counterfeit pedigrees, which imitate authentic pedigrees created by Gilead and accompanied every medication that Scripts sold and distributed, easily meet the use-in-commerce requirement for trademark infringement.

IV. The Frozen Assets Are Significantly Less than Scripts' Counterfeiting Profits

There is no factual basis to modify the asset freeze. Since 2017, Scripts has received over **$137 million** from the sale of counterfeit medication bearing Gilead's registered trademarks with various counterfeit elements, including, at a minimum, counterfeit pedigrees. Dkt. No. 458 ¶¶ 7, 13-15; 2/11/22 Sunkara Decl., Dkt. No. 433 ¶ 7. The money that is currently being frozen is far less than the amount of profits that are subject to disgorgement.

The Seizure Order required Scripts to produce a document showing details of all of its sales and all of its purchases of Gilead-branded product since 2019. Scripts produced a spreadsheet that appeared to correctly list its sales of Gilead-branded medication, but its *purchase* prices were obviously incorrect – the numbers listed were significantly higher than the

actual purchase prices Scripts paid its vendors. Dkt. No. 458 ¶¶ 8-9. As a result, the spreadsheet significantly understated Scripts' profits. *Id.* After several meet and confer sessions, Scripts refused to produce a corrected spreadsheet reflecting Scripts' actual purchase prices. *Id.* ¶ 10. Moreover, Scripts has refused to produce, in response to a discovery request, its purchase and sales information for Gilead-branded products prior to 2019, when it was buying and selling the counterfeits from Mainspring. *Id.* ¶ 12 & Dkt. No. 458-3. However, using the information available to it and making reasonable assumptions therefrom, Gilead has calculated Scripts' counterfeiting profits to be well **over $7.2 million.** *Id.* ¶ 16. Less than $5.5 million of Scripts' funds have been frozen under the stipulated Asset Freeze Order. Dkt. No. 181. Thus, Gilead has frozen significantly less than Scripts' counterfeiting profits. The freeze should remain in place.

V. The Record Confirms Gilead Will Be Irreparably Harmed If the Freeze Is Lifted

Because the Asset Freeze Order is a preliminary injunction, and because Scripts has not attempted to meet its burden by introducing any evidence or even making a single factual representation in its motion, the Court need not reexamine the factual record to deny Scripts motion. That said, above and beyond the evidence that was submitted when the freeze was first implemented, the record in this case is replete with evidence of Scripts' willfulness, intentional fraud, bad faith in dealing with Gilead and the government, financial waste and mismanagement, and inability to pay its creditors. That evidence is more than sufficient to sustain the Asset Freeze Order.

First, as stated previously, the record shows that Scripts, including Mr. Diamantstein himself, worked directly with the street-level collectors at Script's offices, directing them toward which HIV medications to buy from patients because they would move the fastest, and reprimanding them when their counterfeits were too obviously fake because they still showed evidence of having been relabeled after being dispensed to patients. Waters Decl. Exs. 75–79.

See generally Potter Decl. Ex. 354. And most damningly, the evidence shows that **Mr. Diamantstein in fact personally participated in the manufacture of the counterfeits by instructed the collectors to create hundreds upon hundreds of fraudulent pedigrees to facilitate their sale in the legitimate drug supply chain, and personally dictated what the contents of those fraudulent pedigrees should be**. *See, e.g.*, Waters Decl. Ex. 80 (Diamantstein directs Gelbinovich to use an example he provided to create fraudulent pedigrees.). This type of large-scale fraud, aimed at concealing the origin of Scripts' products and creating fake records of "legitimate" sales by Gilead that never occurred, is on its own sufficient grounds to continue the asset freeze. *See S.E.C. v. Manor Nursing Centers*, 458 F. 2d 1082, 1106 (2d Cir. 1972) (affirming freeze where, "[b]ecause of the fraudulent nature of appellants' violations, the court could not be assured that appellants would not waste their assets prior to" disgorging their illicit profits); *S.E.C. v. Credit Bancorp Ltd.*, 2010 WL 768944, at *3 (S.D.N.Y. Mar. 8, 2010) ("A freeze is particularly warranted where the defendant's alleged conduct involves fraud");[5] *Kemp v. Peterson*, 940 F.2d 110, 114 (4th Cir. 1991) ("Although

[5] Because the SEC routinely seeks asset freezes in civil litigations, the bulk of the case law regarding such freezes is in cases brought by the SEC. However, the SEC has no special statutory authority to seek such freezes: in both the SEC context and the Lanham Act, the Court's ability to issue a freeze is based on its inherent equitable powers to freeze illicit profits in aid of the equitable remedy of a disgorgement of illicit profits. *Manor Nursing Centers*, 548 F.2d at 1103-1105, *Levi Strauss & Co. v. Sunrise Int'l Trading, Inc.*, 51 F.3d 982, 987 (11th Cir. 1995) (cited with approval in *Gucci Am., Inc. v. Bank of China*, 768 F.3d 122, 130, 132 (2d Cir. 2014)); *see also Gucci*, 768 F.3d at 130, 132 (agreeing with the three "sister circuits to have considered the issue" that "the district court ha[s] the inherent equitable authority to issue [an] Asset Freeze Injunction" in connection with a claim for profits under the Lanham Act); *Motorola, Inc. v. Abeckaser*, No. 07-CV-3963 (CPS)(SMG), 2009 WL 1362833, at *3 (E.D.N.Y. May 14, 2009) ("[T]he Lanham Act . . . give[s] courts the authority to order equitable relief in the form of an accounting of the seller's profits," a district court "has the authority to order injunctive relief freezing assets in order to ensure availability of final equitable relief"); *Balenciaga Am., Inc. v. Dollinger*, No. 10-CV-2912 (LTS), 2010 WL 3952850, at *7-8 (S.D.N.Y. Oct. 8, 2010) (same and collecting cases); *Reebok Int'l, Ltd. v. Marnatech Enters.,*

'freezing' is an extraordinary remedy, there is no question as to the general authority of the court to fashion the remedy as it did. Such a remedy, of course, must be supported by a showing of fraud, mismanagement, or other reason to believe that, absent the freeze order, the assets would be depleted or otherwise become unavailable.").

Second, the undisputed record shows a clear pattern of how Scripts responds when it is caught selling counterfeits: it lies about its knowledge; it immediately sells off the products it has in stock that it indisputably knows are counterfeit; and it moves on to buy from the next counterfeit supplier. This was Scripts' modus operandi when it was approached by the FBI and learned Mainspring's principal had been arrested for selling bottles of "black market" HIV medication that would "contain 'candy' instead of medication, *see* Dkt. No. 457-8; after the FDA Office of Criminal Investigation told Scripts it was selling HIV medication from Gentek with the wrong pills inside, *see* Dkt. No. 153-2; and after the FDA further identified Abacus as another suspect in their investigation, *see* Dkt. No. 421-3. This is the essence of willful counterfeiting, which itself supports issuance of the freeze. *See Chanel, Inc. v. Sunus Online Group, LLC*, 2014 WL 12558780, at *3 (C.D. Cal. Jan. 15, 2014) ("Based on Defendants' blatant violations of trademark laws there is likelihood that Defendants would transfer or hide the illegally obtained

---

Inc., 970 F.2d 552, 560 (9th Cir. 1992) (such freezes allow courts "to preserve the possibility of an effective accounting of [the counterfeiter's] profits and the return of the profits fraudulently obtained"); *CSC Holdings, Inc. v. Redisi*, 309 F.3d 988, 996 (7th Cir. 2002) ("[S]ince the assets in question . . . were profits [of the defendants] made by unlawfully stealing [the plaintiffs'] services, the freeze was appropriate and may remain in place pending final disposition of this case."). Courts routinely rely in SEC cases in examining asset freezes under the Lanham Act. *See, e.g., Reebok Int'l, Ltd. V. Marnatech Enter.*, Inc., 970 F.2d 552, at 560 (9th Cir. 1992) (relying on FTC and securities cases in assessing district court's authority to issue asset freeze orders); *Levi Strauss & Co.*, 51 F.3d at 987 (11th Cir. 1995) (same); *see also S.E.C. v. Martino*, 255 F. Supp. 2d 268, 289 (S.D.N.Y. 2003) (noting that asset freezes in civil SEC actions are based in the Court's inherent powers).

assets in order to avoid a judgment in this action."); *ABG EPE IP, LLC v. 3C Smart Store*, 2021 WL 2452636 at *1 (N.D. Ga. Apr. 17, 2021) ("Such asset freezes are particularly appropriate against sellers of counterfeit goods who are likely to hide their ill-gotten profits if their assets are not seized.") (citing *Reebok Intern., Ltd. v. Marnatech Enterprises, Inc.*, 970 F.2d 552, 559 (9th Cir. 1992)). But even further, this evidence shows that when Scripts is caught red-handed selling fake HIV medication, its pattern and practice is to lie, conceal evidence, and move onto the next scam. On this record, Scripts certainly cannot be trusted to maintain its illicit profits to pay a judgment to Gilead. *See, e.g.*, *U.S. Dept. of Hous. & Urb. Dev. v. Cost Control Mktg. & Sales Mgmt. of Va., Inc.*, 64 F.3d 920, 927 (4th Cir. 1995) (affirming asset freeze where district court concluded "the individual defendants cannot be trusted to conserve their assets.")

Third, the undisputed evidence shows that Scripts is the longest-running counterfeiter of Gilead-branded HIV medication in this case, having continually sold counterfeits for over five years – up until the day that Gilead served the Asset Freeze Order upon Scripts. On the day that the freeze was implemented, Gilead seized over a thousand bottles of counterfeit Gilead-branded HIV medication from Scripts' shelves, all with fraudulent pedigrees and most of them with either counterfeit outserts or no outserts at all, ready to be shipped to unsuspecting pharmacies. Unlike the cases that Scripts cites in its briefing, Scripts' willful counterfeiting was not a short-term offense that occurred well before its assets were frozen. Scripts' core business was the sale of counterfeit HIV medication for half a decade, and continued until the moment that this Court enjoined their sales and froze its assets.

Fourth, the record shows that Scripts repeatedly pushed itself to the brink of financial ruin by pouring its illicit profits into further expanding its counterfeiting operation. Mr. Diamantstein simply handed over approximately $5 million – about the amount that Gilead had

frozen – to a criminal counterfeiter for the express purpose of financing the counterfeiter's supply of HIV medication**,** with no contract, no written guarantees, and no paper trail to support or protect this "investment." Dkt. No. 457-3. Utterly unsurprisingly, the counterfeiter took Scripts' $5 million and kept it. Scripts then became directly involved in the purchase of HIV medication from patients on the street for cash, and kept a safe full of cash and pre-paid credit cards in its office for that purpose. Dkt. No. 460. And throughout the course of the past five years, Mr. Diamantstein kept his counterfeiting operation running by maxing out an ever-revolving line of credit cards, relying on his father's credit, and writing checks to suppliers with instructions not to deposit them because they would bounce. *See, e.g.*, Dkt. No. 608-30.

Fifth, and finally, Mr. Diamantstein, Scripts' owner and president, and the signatory on its bank accounts, has already openly stated before this Court that he will plead the Fifth Amendment in this action in response to any and all questions he is asked under oath, because there is a current federal criminal investigation of his counterfeiting of Gilead-branded products. Dkt. No. 1012, Ex. A ¶ 6. Mr. Diamantstein in fact directly admitted that if deposed he would take the Fifth with regard to all questions relevant to the instant motion to vacate the stay. *Id.* Diamantstein successfully moved to stay his deposition in light of the criminal investigation against him and his intent to take assert his Fifth Amendment privileges. *See* ECF Order, entered April 27, 2023. Thus, the Court can and should assume that Diamantstein will refuse to answer all questions relevant to the instant motion, and draw adverse inferences against him. *See In re 650 Fifth Ave. and Related Props.*, 934 F.3d 147, 171 (2d Cir. 2019); *United States v. Ianniello*, 646 F. Supp. 1289, 1296 (S.D.N.Y. 1986), *aff'd*, 824 F.2d 203 (2d Cir. 1987) ("[I]n civil cases a party's Fifth Amendment refusal to testify may form the basis for an adverse factual inference[] . . . including] in the context of a motion for preliminary equitable relief."); *see, e.g.*, *S.E.C. v.*

Princeton Econ. Intern. Ltd., 1999 WL 997149, at *3 (S.D.N.Y. Nov. 3, 1999) (drawing adverse inference in light of Fifth Amendment invocation and granting preliminary injunction). Otherwise, as noted above, Gilead will take Mr. Diamantstein's testimony at the preliminary injunction hearing, and the same result will obtain when he asserts his Fifth Amendment privileges in response to questioning at that time. Gilead will question Mr. Diamantstein on facts directly relevant to this motion, including those listed above. Especially at the preliminary injunction stage, the Court can and should draw negative inferences from Mr. Diamantstein's assertion of the Fifth Amendment, and hold that his taking the Fifth further supports a continuation of the freeze.

As a counterfeiter, Scripts holds its illicit profits in trust for Gilead. *See George Basch Co. v. Blue Coral, Inc.,* 968 F.2d 1532 (2d Cir. 1992) ("Thus, a defendant who is liable in a trademark or trade dress infringement action may be deemed to hold its profits in constructive trust for the injured plaintiff."). On this record, there is little question that if the asset freeze is lifted and Scripts is able to freely spend the frozen funds, those illicit profits will be unavailable to disgorge to Gilead.

VI. The Balance of the Equities Tips Decidedly in Favor of Gilead

This Court has already decided, based on the relatively limited evidence before it when Gilead first moved for the Asset Freeze Order, that the balance of the equities was in Gilead's favor. The record has only gotten worse for Scripts, and it has no serious argument that the Court should reverse its earlier judgment. Scripts does not so much as argue that it is prejudiced by the asset freeze, or that needs any of the frozen funds to continue any remaining legitimate business it may have. The balance of the equities continues remains decidedly in favor of the legitimate manufacturer of life-saving medications, and against the willful counterfeiter that

helped manufacture and unlawfully sold thousands of counterfeits HIV medication with fake pills, fake patient instructions, and fake pedigrees.

CONCLUSION

The Court should hold that Scripts bears the burden of proof, through documentary evidence, on its motion to amend the Asset Freeze Order, and deny the motion out of hand because Scripts makes no attempt to meet that burden. In the alternative, for the reasons stated above, the Court should deny Scripts' motion and hold that the amended Asset Freeze Order shall remain in effect during the pendency of this litigation.

Dated: May 30, 2023

Respectfully submitted,

Geoffrey Potter
Timothy A. Waters
Thomas P. Kurland
Gizele Rubeiz
Angelica H. Nguyen

PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
Tel: (212) 336-2000
Fax: (212) 336-2222
gpotter@pbwt.com
twaters@pbwt.com
tkurland@pbwt.com
grubeiz@pbwt.com
anguyen@pbwt.com

Attorneys for Plaintiffs
Gilead Sciences, Inc., Gilead Sciences Ireland UC, and Gilead Sciences, LLC